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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/339,352	06/23/99	REED-GITOMER B	UTSD:553

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EXAMINER	
ROBINSON,H	
ART UNIT	**PAPER NUMBER**
1653	5

DATE MAILED: 10/21/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/339,352	Reed-Gitomer et al.
Examiner	**Group Art Unit**
Hope Robinson	1653

☒ Responsive to communication(s) filed on *Jun 23, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-26* is/are pending in the application.

Of the above, claim(s) *16 and 18-26* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-15 and 17* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) as follows:

The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971).

The examiner read the provisional application and did not find support for sequences recited in the claims and disclosed in the specification (SEQ ID No. 1 which encodes the protein contained in SEQ ID No.2) of the current application. Furthermore, the provisional application did not disclose the marker D1S2681 wherein the genomic region of the invention is comprised. Therefore, this application will not get the Priority date of the provisional application only the filing date of the present application which is June 23, 1999.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15 and 17 are drawn to method for screening increased risk of hypercalciuria, classified in class 435, subclass 6.

II. Claims 16 and 18-25 are drawn to a method of treating hypercalciuria, classified in class 514, subclass 2.

III. Claim 26 is drawn to a method for screening increased risk of absorptive hypercalciuria or osteoporosis with hypercalciuria, classified in class 435, subclass 6.

The inventions are distinct, each from the other because the following reasons:

Invention I is patentably distinct from the methods of Invention II because the screening method of Invention I utilizes differing reagents and its end point is risk assessment while Invention II provides for an undisclosed screening method combined with a method of treatment. Therefore, the reagents and end point of Invention II are separate and distinct from those of Invention I.

Invention I is patentably distinct from the method of screening in Invention III because of the difference in scope of the claim and the different method steps.

Invention II is distinct from Invention III since Invention II is a method of treating the disease and Invention III is a method of screening the disease.

For these reasons restriction for examination purposed is proper.

During a telephone conversation with Mr. Mark Wilson on September 27, 1999 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-15 and 17. Affirmation of this election must be made by applicant in responding to this Office action. Claims 16 and 18-26 are withdrawn from further consideration by the Examiner, 37 CFR 1.142 (b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor-ship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor-ship must be accompanied by a diligently filed petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (h).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention. The claimed invention is enabled for the nucleic acid sequence contained in SEQ ID No. 1 that encodes a protein contained in SEQ ID No. 2, however, does not reasonably provide enablement for any hypercalciuria gene . The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. In *Ex parte Forman*, 230 USPQ 546 (Bd. App. 1986), the Board considered the issue of enablement in molecular biology. The Board summarized eight factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement

requirement and whether any necessary experimentation is undue. These factors include, but are not limited to:

I. Quantity of Experimentation Necessary:

The claimed invention refers to the detection of the presence or absence of a genetic mutation in the genomic region associated with an increased risk of hypercalciuria, it does not teach what gene is associated with hypercalciuria. Therefore, it would warrant undue experimentation for other genes in hypercalciuria (see page 7 of specification). In addition, the specification does not teach which mutation in SEQ ID No. 1 is associated with an increased risk of hypercalciuria (see page 8 and 9 of specification).

Furthermore, the specification lacks complete deposit information for Gen Bank Accession numbers recited in the claims in the current application, which is critical or essential to the practice of the invention, but not included in the claim (s) is not enabled by the disclosure (see *In re Mayhew*, 527 1229, 188 USPQ 356 (CCPA 19 76).

The genomic region associated with an increased risk of Absorptive Hypercalciuria may have a sequence contained in at least one genetic sequence selected from the group of sequences set forth in the Gen Bank Accession numbers. Therefore, it is not known whether the genetic sequence of the invention contained in the sequences at Gen Bank is known and publicly available or can be reproducibly isolated. Without publicly available deposit information one of skill in the art could not be assured of the ability to practice the invention as claimed.

Applicant's referral to the deposit of the sequences to Gen Bank on page 6 of the specification is noted but is considered insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. If deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 CFR 1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(A) During the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(B) All restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(C) The deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(D) The deposits were viable at the time of deposit;

(E) The deposits will be replaced if they should ever become non-viable.

This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State. Amendment of the specification to disclose the date of the deposit and the complete name and address of the depository is required.

For further information concerning deposit practice, applicants attention is directed to *In re Lundark* 773 F 2d 1216 227 USPQ CCAFC and 37 CFR 1.801-1.809.

II. Amount of direction or guidance presented:

The specification does not disclose one reasonable method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim. Therefore, one skilled in the art at the time of the invention would not be able to make or use the claimed invention.

Furthermore, no clear direction or guidance is given in the disclosure as to which genetic sequence is set forth in Gen Bank Accession #'s Z97876, Z999453 and AL031733 which has the sequence contained in the genomic region associated with an increased risk of absorptive hypercalciuria. Additionally, no information was provided regarding the deposit and it is unclear whether the deposit was made under the Budapest Treaty guidelines.

III. Presence or absence of working examples:

Only one working example of the invention was provided that being SEQ ID No. 1 encoding a protein contained in SEQ ID No. 2. The nature and properties of this claim is difficult to ascertain from this one record.

IV. Nature of the Invention:

The present invention relates to the discovery that there exists an area on human chromosome 1 that is genetically linked to absorptive hypercalciuria and some forms of osteoporosis. The invention further relates to the development of a familial screening method.

The invention is very complex and requires a high level of skill. Additionally, the specification does not disclose many methods for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim.

V. State of the prior art and Relative skill of those in the art:

It is disclosed in the specification that the mechanism by which hypercalciuria leads to osteoporosis is not fully understood (see page 2 of specification). Furthermore, the invention is complex and since there is no analogous art, at the time of the invention a high level of skill is required. Therefore, the specification at the time the application was filed, would not have taught one skilled in the art how to make and or use the full scope of the claimed invention without undue experimentation.

VI. Predictability or unpredictability of the art:

Since very little is known in the prior art about the nature of the invention renders the art unpredictable. The specification should then give more details as to how to make and use the invention in order to be enabling. One skilled in the art would have a difficult time understanding, using and making the invention as claimed.

VII. Breadth of the claims:

The breadth of the claims are very broad in scope and encompass information not supported in the specification.

For all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indifinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is apparent that the genetic sequences set forth in Gen Bank Accession Numbers Z97876, Z99943 and AL031733 are required to practice the claimed invention, yet it is unclear what these sequences are since they are not listed in the application. Applicant needs to submit sequence listings for all sequences contained in the above accession numbers in order to comply with 37 CFR 1.821 because this is essential matter.

Art of Record

5. The following references are being submitted as evidence that the claimed sequences are well known in the art:

Rhodes (Rhodes S, Jan. 6, 1999) teach the identical sequence claimed by the applicant contained in SEQ ID No. 1 (see the attached paper copy of the alignment printout). Rhodes teach that this sequence was generated from cDNA clones isolated using sequence from bacterial clones. As the sequences reported by Rhodes are 100% identical to those in the instant application, the sequence limitations of the claims are met by the DNA disclosed by Rhodes. However, Rhodes does not teach a method of screening for increased risk for Hypercalciuria.

Grafham (Grafham D, October 27, 1997) teach the identical sequence claimed in Gen Bank Accession Number Z97876 (see the attached paper copy of the alignment printout). Grafham teach that this sequence was generated from part of a bacterial clone contigs of human chromosome 1. The sequences reported by Grafham are 73% identical to those in the instant application, therefore, the sequence limitations of the claims are met by the DNA disclosed by Grafham.

Conclusion

6. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 7.00 am to 3.30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

Hope Robinson, MS

Patent Examiner